REMARKS

In the Office Action of October 10, 2002, Claims 1 - 30 were rejected. No claim was allowed. In response, and further to a Request for Continued Examination submitted herewith, Claims 1, 2, 5, 7, 9, 13, 17, 21, 23 and 27 are amended. Reexamination and reconsideration are respectfully requested in view of the foregoing amendments and the following remarks.

Objection to Information Disclosure Statement

The Examiner objected to the Information Disclosure Statements submitted on August 15, 2001 and June 3, 2002. The Examiner required revision of the list of documents submitted on August 15, 2001 to show the Japanese Patents under the heading of Foreign Patent Documents. The Examiner's statement that a list of documents was not provided in the Information Disclosure Statement of June 3, 2002 is not understood, since Applicant's records show that a form PTO 1449 was submitted. A revision of the PTO form 1449 submitted on August 15, 2001 and a copy of the PTO form 1449 submitted on June 3, 2002 are attached hereto.

Rejection of Claims 1 - 30 under 35 U.S.C. §112, first paragraph

Claims 1 - 30 were rejected under 35 U.S.C. §112, first paragraph, as containing subject matter that is not enabled by the specification. The Examiner alleged that the specification, while being enabling for peptides, proteins, enzymes and amino acid derivatives, does not provide enablement for all compounds having free amino groups. The Examiner took the position that to claim all compounds having a free amino group is to claim too broad coverage for the applicant's

invention.

In response, Claims 1 and 5 are amended to conform what the Examiner has acknowledged is enabled by the specification, specifically, doxorubicin, peptides, proteins, enzymes and amino acid derivatives.

Accordingly, it is respectfully submitted that the rejection of Claims 1 - 30 under 35 U.S.C. §112, first paragraph, is thereby overcome.

Rejection of Claims 2 and 5 - 30 under 35 U.S.C. §112, second paragraph

Claims 2 and 5 - 30 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite. The rejection as applied to Claim 2 was not explained. The Examiner alleged that the phrase "modified with or included in" renders Claims 5 and 9 vague, unclear and confusing.

In response, Claims 5, 7, 9, 13, 17, 21, 23 and 27 are amended for greater clarity. Further, the rejection is respectfully traversed to the extent that the Examiner takes the position that the phrase "modified with or included in a pharmaceutical carrier" is indefinite. Pharmaceutical carriers are described in detail in the specification on page 6, and the phrase "modified with or included in" would be clear to persons skilled in the art as encompassing the range of possible interactions that the listed compounds may have with the carrier.

Accordingly, it is respectfully submitted that Claims 2 and 5 - 30 are not indefinite. Withdrawal of the rejection under 35 U.S.C. §112, second paragraph, is respectfully requested.

Rejection of Claims 1 - 4 under 35 U.S.C. §102(b) over Katsukiyo

Claims 1 - 4 were rejected under 35 U.S.C. §102(b) as anticipated by Katsukito (JP 7-61999). The Examiner alleges that Katsukito teaches a sugar-modified protein obtained when lactose-lactone is reacted with a protein, and that it also describes using insulin as the protein. The Examiner takes the position that the reference inherently teaches that a free protein can be quickly separated through changes in pH.

This rejection is respectfully traversed as it may be applied to the claims as amended herein. In particular, Claim 1 is amended to provide that a new amide bond is not formed by the reaction of a compound having a free amide group and a sugar having reducing power. JP 7-61999 (Katsukiyo) discloses a sugar-modified protein obtained when lactose-lactone is reacted with a protein in a reaction in which an amide bond is formed. Accordingly, JP 7-61999 does not disclose the claimed invention as amended herein.

Accordingly, it is respectfully submitted that Claims 1 - 4 are not anticipated by Katsukiyo.

Rejection of Claim 1 - 30 under 35 U.S.C. §103(a) over Takenaga et al in view of Katsukiyo and Masashi

Claims 1 - 30 were rejected under 35 U.S.C. §103(a) over Takenaga (U.S. Patent No. 5,723,121), in view of Katsukito and Masashi (JP 9-263579). The Examiner alleges that Takenaga disclose modifying interferon-a by reacting the interferon with a solution of lactose lactone in sodium dodecyl sulfate and preparing a pharmaceutical preparation by combining the resultant chemical compound with

albumin. The Examiner alleges that the modified compound would intrinsically function as claimed because the prior art composition is comprised of the same components, a compound having a free amino group modified with a reducing sugar. The Examiner acknowledges that Takenada does not disclose insulin to be the peptide with free amino group and does not clearly disclose a pharmaceutical carrier. The Examiner alleges that Katsukiyo teaches a sugar-modified protein obtain when lactose-lactone is reacted with a protein and describes using insulin as the protein and that the reference inherently teaches that a free protein can be quickly separated through changes in pH. The Examiner alleges that Masashi et al teach medicines made from the enclosing of a drug made from protein inserted into a micro-globule, ribosome, emulsion or other carrier. The Examiner takes the position that it would have been obvious to modify the composition and method of Takenaga according to the teachings of Katsukiyo and Masashi because both Takenaga and Katsukiyo teach modifying a compound having a free amino group with a reducing sugar wherein upon changes in the pH conditions, the compound with the free amino group is released and because Masahi teaches making a drug by inserting a protein into a microglobule, ribosome, emulsion or other carrier.

This rejection is traversed. As discussed above, Claim 1 is amended to provide that in the compound of the present invention, a new amide bond is not formed by the reaction of a compound having a free amide group and a sugar having reducing power. The references cited by the Examiner all relate to compounds having newly formed amide bonds. Accordingly, these references do not disclose the claimed invention as amended herein. Further, the cited references do not disclose nor suggest a pharmaceutical preparation capable of rapidly releasing a

compound having a free amino group in response to changes in pH, which effect cannot be achieved if the compound to be released is attached by an amide bond. Thus, it would not obvious to a person of ordinary skill in the art to make the pharmaceutical preparation claimed in the present claims as amended over Takenaga, Katsukito and Masashi. Accordingly, it is respectfully submitted that Claims 1 - 30 would not have been obvious over Takenaga, Katsukito and Masashi, alone or in combination.

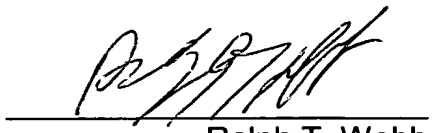
Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that Claims 1 - 30 are in condition for allowance. Favorable reconsideration is respectfully requested.

Should the Examiner believe that anything further is necessary to place this application in condition for allowance, the Examiner is requested to contact applicants' undersigned attorney at the telephone number listed below.

Kindly charge any additional fees due, or credit overpayment of fees, to Deposit Account No. 01-2135 (506.40278X00).

Respectfully submitted,
ANTONELLI, TERRY, STOUT & KRAUS



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Enclosures:
(1) Modified PTO Form 1449 submitted August 15, 2001.
(2) Copy of PTO Form 1449 submitted on June 3, 2002

Marked up copy to show changes

IN THE CLAIMS

1. (amended) A pharmaceutical preparation comprising a compound (i) which can be obtained by reacting a compound having a free amino group, said compound having a free amino group being selected from the group consisting of doxorubicin, peptides, proteins, enzymes and amino acid derivatives, with a sugar having the reducing power, wherein a new amide bond is not formed by the reaction, and (ii) which is capable of rapidly releasing ~~the~~ said compound having a free amino group in response to changes in pH.

2. (amended) The preparation according to claim 1, wherein said compound having a free amino group selected from the group consisting of doxorubicin, peptides, proteins, enzymes and amino acid derivatives is a pharmaceutical compound.

5. (amended) The preparation according to claim 1, wherein at least one of said compound having a free amino group selected from the group consisting of doxorubicin, peptides, proteins, enzymes and amino acid derivatives, said sugar having the reducing power, ~~or~~ and said compound which can be obtained by reacting ~~a~~ said compound having a free amino group with ~~a~~ said sugar having the reducing power is modified with, or included in a pharmaceutical carrier.

7. (amended) The preparation according to claim 5 or 6, wherein said compound having a free amino group selected from the group consisting of doxorubicin, peptides, proteins, enzymes and amino acid derivatives is included in said

pharmaceutical carrier.

9. (amended) The preparation according to claim 2, wherein at least one of said pharmaceutical compound, said sugar having the reducing power, ~~or~~ and said compound which can be obtained by reacting ~~a~~ said pharmaceutical compound with ~~a~~ said sugar having the reducing power, is modified with or included in a pharmaceutical carrier.

13. (amended) The preparation according to claim 3, wherein at least one of said compound having a free amino group selected from the group consisting of peptides, proteins, enzymes and amino acid derivatives, said sugar having the reducing power, ~~or~~ and said compound which can be obtained by reacting ~~the~~ said compound having a free amino group ~~selected from the group consisting of peptides, proteins, enzymes and amino acid derivatives~~ with ~~a~~ said sugar having the reducing power is modified with or included in a pharmaceutical carrier.

17. (amended) The preparation according to Claim 4, wherein at least one of insulin, said sugar having the reducing power, ~~or~~ and said compound which can be obtained by reacting insulin with ~~a~~ said sugar having the reducing power is modified with or included in a pharmaceutical carrier.

21. (amended) The preparation according to claim 1, wherein said compound having a free amino group selected from the group consisting of doxorubicin, peptides, proteins, enzymes and amino acid derivatives is a peptide.

23. (amended) The preparation according to claim 21, wherein at least one of said peptide, said sugar having the reducing power, ~~or~~ and said compound which can be obtained by reacting ~~a~~ said peptide with ~~a~~ said sugar having the reducing power, is modified with or included in a pharmaceutical carrier.

27. (amended) The preparation according to claim 22, wherein at least one of enkephalin, said sugar having the reducing power, ~~or~~ and said compound which can be obtained by reacting enkephalin with ~~a~~ said sugar having the reducing power, is modified with or included in a pharmaceutical carrier.